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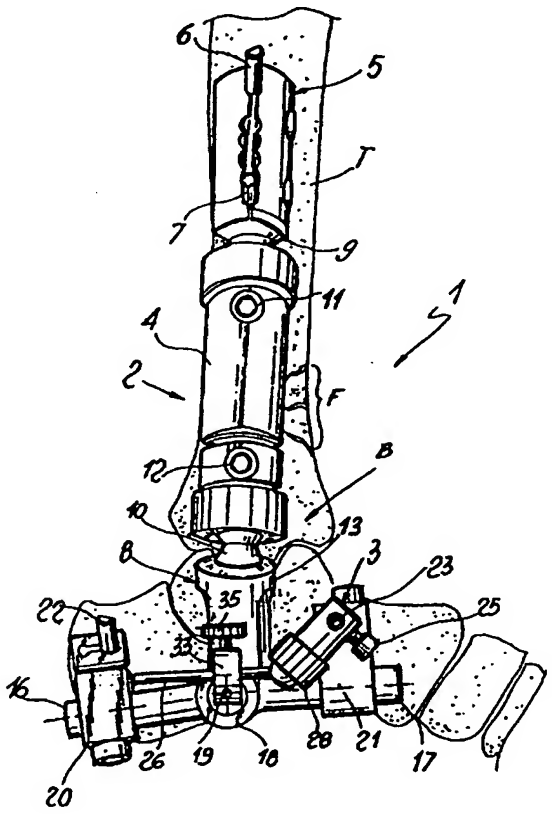
(54) Title: APPARATUS FOR TREATING ANKLE FRACTURES

(57) Abstract

An apparatus for treating ankle fractures includes an external fixer formed by a tibial clamp and a heel clamp connected to a central member extendable by means of respective universal joints. The heel clamp is articulated such that its rotation axis is arrangeable to be approximately centered on the tibial-heel joint axis. The apparatus also includes a positioner device of the true rotation axis of the tibial-heel joint, wherein such device includes a support removably associated with a screw freely insertable in the astragalus, a Kirschner string adapted to identify said true rotation axis, a locking member of the Kirschner string selectively orientable with respect to the support until the axis of the string is substantially stationary during the rotation of the tibial-heel joint.



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APPARATUS FOR TREATING ANKLE FRACTURES

The present invention relates to an apparatus for treating ankle fractures.

A conventional technique for treating ankle fractures includes the use of an external fixer comprising a proximal clamp anchored to two screws inserted in the tibial diaphysis and a distal clamp anchored to a screw inserted in the calcaneus and in the tarsus; both clamps are connected to a central member which can be extended by means of universal joints.

The particular distal clamp is articulated in order to rotate about an axis which approximately coincides with that of the tibial-heel joint. The rotating axis is placed by hand and is usually identified by means of a Kirschner string fixed in the tarsal sinus.

A first inconvenience of the above fixing technique is that the axis of the distal clamp rarely coincides with the true axis of the tibial joint and this causes diastasis and compressions to the joint and tractions to the ligaments.

Secondly, once the position of the articular rotation axis has been determined, the relative position of the calcaneus and heel screws remains fixed with a consequent limitation of the insertion of the clamp and a difficult positioning of the fixer.

A main aim of the present invention is to eliminate the above mentioned drawbacks by providing an apparatus adapted to maintain a correct articulation of the tibial joint helping the rehabilitation and speeding the recovery.

A further aim is that of providing an apparatus adapted to ease the insertion of the distal screws allowing maximum freedom in placing the screws in order to reduce the operating time and the exposure to X rays.

According to one preferred aspect of the invention, there is provided an apparatus for treating ankle fractures comprising: an external fixer formed by a tibial clamp and a heel clamp connected to a central member extendable by means of respective universal joints, said heel clamp being articulated such that its rotation axis is arrangeable to be approximately centered on the tibial-heel joint axis; a positioner device of the true rotation axis of the tibial-heel joint, wherein said device comprises a support removably associated with a screw freely insertable in the astragalus, a Kirschner string adapted to identify said true rotation axis, a locking member of said Kirschner string selectively orientatable with respect to said support until the axis of said string is substantially still during the rotation of the tibial-heel joint.

The particular characteristics and advantages of the invention will be more apparent by the following detailed description of some preferred embodiments of the apparatus according to the invention, illustrated by way of non-limiting example in the enclosed drawings wherein:

FIG. 1 is a side view of an apparatus according to the invention installed at a tibial-heel joint;

FIG. 2 is a slightly elevated perspective front view of the

apparatus of FIG. 1;

FIG. 3 is a lower perspective view of the apparatus of FIG. 1;

FIG. 4 shows the apparatus of FIG. 1 without the distal clamp in order to better show the device for identifying the true axis of the joint;

FIG. 5 is a side view of a part of a first embodiment of the distal clamp;

FIG. 6 is a section view according to the plane VI-VI of FIG. 5;

FIG. 7 is a section view of another component of a distal clamp;

FIG. 8 is a front view of a further component of a distal clamp;

FIG. 9 is a section view according to the plane IX-IX of FIG. 8;

FIG. 10 is a section view of a variated embodiment of the component of FIG. 9;

FIG. 11 is an exploded side view of a device which is part of the apparatus according to the invention;

FIG. 12 is a side partial view of a second embodiment of a distal clamp; and

FIG. 13 is a section view according to the plane XIII-XIII of FIG. 5.

With reference to the above figures, an apparatus according to the invention, generally designated by the reference numeral 1, is used to consolidate an ankle fracture with a nidus F localized, for example, towards the lower part of the tibia T proximate to the tibial-heel joint B, more clearly visible in FIG. 4.

The apparatus comprises an axial fixer 2 and a device 3 for identifying and positioning the true axis of joint B.

Namely, axial fixer 2 comprises a per se known extendable central member 4 connecting a proximal clamp 5, anchored to two tibial screws 6 and 7, and a distal clamp, generally designated by the reference numeral 8, which will be described in more detail hereinafter.

Proximal clamp 5 and distal clamp 8 are connected to the central member by means of universal spherical joints 9, 10, provided with locking eccentric members 11, 12 protruding from central member 4 with Allen screws.

Distal clamp 8 is articulated, as shown in detail in FIGs. 5and 6, and comprises an extended fork 13 having two relatively thin longitudinal walls 14, 15. Two radial appendixes 16, 17 are associated with walls 14, 15 on a transversal axis c arranged at the free ends.

The pivotal axis of the clamp is defined by a bush 18 having

a central through bore 19.

The bush also constitutes a first stop member of radial appendixes 16, 17 and has an hexagonal external profile shaped as a nut screw. By rotating of the bush by means of a wrench the rotation of the two appendixes is blocked with respect of fork 13.

Respective universal clamps 20,21 are associated with radial appendixes 16, 17 for anchoring to two distal screws 22, 23.

FIGs. 12 and 13 show a second embodiment of the distal clamp wherein like reference characters, provided with apostrophes, denote similar features.

In particular, a clamp 8' is different from the above described one in that it comprises two independent stop members of the arms constituted by a double stop bush: a first inner bush 18', centrally provided with a central hexagonal bore adapted to lock radial appendixes 16', 17' with respect to fork 13', and a second external bush 18", provided with perpendicular diametral bores for locking the relative rotation of the two radial appendixes 16', 17'.

The positioning and identifying device 3 is adapted to search the true axis of the tibial-heel joint. Such true axis will be designated by the reference sign a on the figures.

Device 3 is illustrated in more detail in FIG. 11 and comprises a substantially cylindrical hollow support 24 having an end bore adapted to accommodate a screw 23,

inserted in the astragalus, and locked by a lock screw 25.

It is to be noted that screw 23 can be positioned by hand with no particular inclination taking only good care of not damaging the blood vessels and the ligaments that are particularly delicate in this region.

A rod 26 may be connected to support 24 by means of a spherical joint. Such spherical joint is constituted by a sphere 27 formed at the end of rod 26 and adapted to be inserted in the internal cavity of support 24 and locked therein by means of a threaded ring 28 provided with an inner conical abutment 29.

An eccentric pin 30, inserted in a transversal through bore of the cylindrical support 24 is adapted to compress sphere 27 towards conical abutment 29 of ring 28 by means of a bearing 31 having a substantially hemispherical cavity 32.

An annular member 33 can be mounted on rod 26 and has a central bore having an inner diameter which is slightly greater than the diameter of the rod in order to allow a desired rotation and sliding. The annular member is also provided with a transversal bore 34 which is staggered with respect of the axis for the passage of a Kirschner string. The position of the annular member 33 and the orientation of the transversal bore 34, and therefore of the Kirschner string K, can be locked by means of a lock screw 35 as shown in FIGs. 1 to 4.

FIGs. 7 to 10 schematically show side and section views of orientable prismatic clamps adapted to connect the radial

appendixes 16, 17 and respectively, 16', 17' of radial clamp 8 or 8', to the heel and astragalus screws 22 without any limitation in choosing their position with respect of the Kirschner string K. Advantageously, all the clamps shown in FIGs. 7 to 10 have a main prismatic body 36 having a through bore 37 for the passage of radial appendixes 16, 17, 16', 17', and a secondary body 38 having a through bore 39 having a smaller diameter for locking screws 22, 23. The two bodies are locked together by means of a transversal general Allen screw 40.

Operatively, the surgeon will insert the tibial screws 6, 7 and the clamp 5 on the screws, then the surgeon will connect the central member 4 by tightening the eccentric 11. After inserting a screw 23 in the astragalus by hand, i.e. without any specific inclination, the surgeon will anchor the support of device 3 to the screw 23. Once the axis of the tibial-heel joint B has been determined with a good approximation and once that point has been marked on the patient's skin, the surgeon will position the device 3 with the Kirschner string centered on that point. After locking the Kirschner string with respect of the screw 23, the surgeon will make the joint turn. If the Kirschner string moves eccentrically with respect of the point marked on the patient, that means that its position does not yet correspond to the true axis of the joint. Therefore, by sliding and rotating the annular member 34 about two axes, the Kirschner string will be moved and oriented to make its axis substantially still as the joint rotates. In this condition the axis of the Kirschner string coincides, with a good approximation, with the true axis of the tibial-heel joint preventing excessive diastasis and/or compression of

the joint bones.

After finally locking the device 3 with clamp 21, the surgeon will position the distal clamp to articulate it such that its pivoting axis coincides with the axis of the Kirschner string. The surgeon will then insert the calcaneus screw 22 in a free position thanks to the orientable prismatic clamp 20.

All the screws, the eccentric elements and the inner bush 18' of distal clamp 8' can now be locked in order to prevent the mutual rotation of the two radial appendixes 16,17 and in order to ease the stabilization of the fracture.

After a certain time selected by experience, the surgeon will free the tibial-heel joint by loosening the screw 19 in order to allow the correct rotation of the joint, making the fracture dynamic and sensibly accelerating the rehabilitation.

It is apparent from the above description that the apparatus according to the invention achieves all the intended objects and in particular the search for the true axis of rotation of the joint and the freedom in positioning the distal screws.

The material employed for the axial fixer and for the positioning device are chosen among the stainless steels, light alloys, and the biocompatible special metals according to the standards set forth by the International medical and quality specifications.

The apparatus according to the invention may have numerous modifications and variations, all within the scope of the appended claims.

Size, shapes and materials may be modified without departing from the inventive concept.

Where technical features mentioned in any claim are followed by reference signs, those reference signs have been included for the sole purpose of increasing the intelligibility of the claims and accordingly, such reference signs do not have any limiting effect on the scope of each element identified by way of example by such reference signs.

C L A I M S

1. An apparatus for treating ankle fractures comprising: an external fixer formed by a tibial clamp and a heel clamp connected to a central member extendable by means of respective universal joints, said heel clamp being articulated such that its rotation axis is arrangeable to be approximately centered on the tibial-heel joint axis; a positioner device of the true rotation axis of the tibial-heel joint, wherein said device comprises a support removably associated with a screw freely insertable in the astragalus, a Kirschner string adapted to identify said true rotation axis, a locking member of said Kirschner string selectively orientatable with respect to said support until the axis of said string is substantially stationary during the rotation of the tibial-heel joint.

2. The apparatus, according to claim 1, wherein said support comprises a block having a through bore for the passage of the bone screw inserted in the astragalus, and a screw for locking said screw in said bore.

3. The apparatus, according to claim 1, wherein said rod is coupled to the free end of said block by means of a spherical joint provided with locking means.

4. The apparatus, according to claim 1, wherein said rod slidingly and rotatably supports an annular member provided with a lateral bore which is perpendicular and staggered with respect of said rod for the passage of said Kirschner string.

5. The apparatus, according to claim 4, comprising locking

means for locking said annular member and said Kirschner string in selected positions.

6. The apparatus, according to claim 1, wherein said articulated distal clamp comprises a fork member having longitudinal arms and a transversal pivoting axis arranged at the ends of said arms.

7. The apparatus, according to claim 6, wherein said pair of radial appendixes is pivoted to said arm for supporting a pair of orientable clamps in an adjustable position, said clamps being associable with said calcaneus screw, inserted in the astragalus, in freely chosen positions.

8. The apparatus, according to claim 7, wherein said arms have a reduced thickness sufficient to allow the passage of X rays of adapted intensity and strength.

9. The apparatus, according to claim 7, wherein a guide bore for guiding said string is provided at the rotation axis of said distal clamp.

10. The apparatus, according to claim 7, wherein said radial appendixes are mounted on said pivoting axis defining a predetermined fixed angle between each other, first stop means being provided for locking the rotation of said appendixes.

11. The apparatus, according to claim 7, wherein said appendixes are mounted on said pivoting axis with the possibility of variating the angle between each other, first stop means being provided for locking the rotation of said

appendixes and second stop means being provided independent from said first means for fixing the angle between said appendixes.

12. A method for treating ankle fractures comprising the steps of:

providing an apparatus comprising an axial fixer having a fixed proximal clamp and an articulated distal clamp having a pivoting axis and radial appendixes, joined by a central member extendable by means of universal joints, providing a device for determining the true rotation axis of the tibial-heel joint provided with a pivoting axis having a guide bore for a Kirschner string;

inserting at least one screw in a tibial diaphysis proximate to the fracture;

anchoring said proximal clamp on said tibial screw and connecting said clamp to said central member;

inserting by free hand a distal screw in the astragalus and a second distal screw in the calcaneus;

removably anchoring said device to said screw;

determining the true axis of rotation by orienting and selectively locking a Kirschner string to the end of said device and by rotating the tibial-heel joint until during said rotation the axis of said string is substantially stationary;

centering the pivoting axis on said Kirschner string and connecting the clamp to said central member; and

anchoring said radial appendixes of said distal clamp to said distal screws.

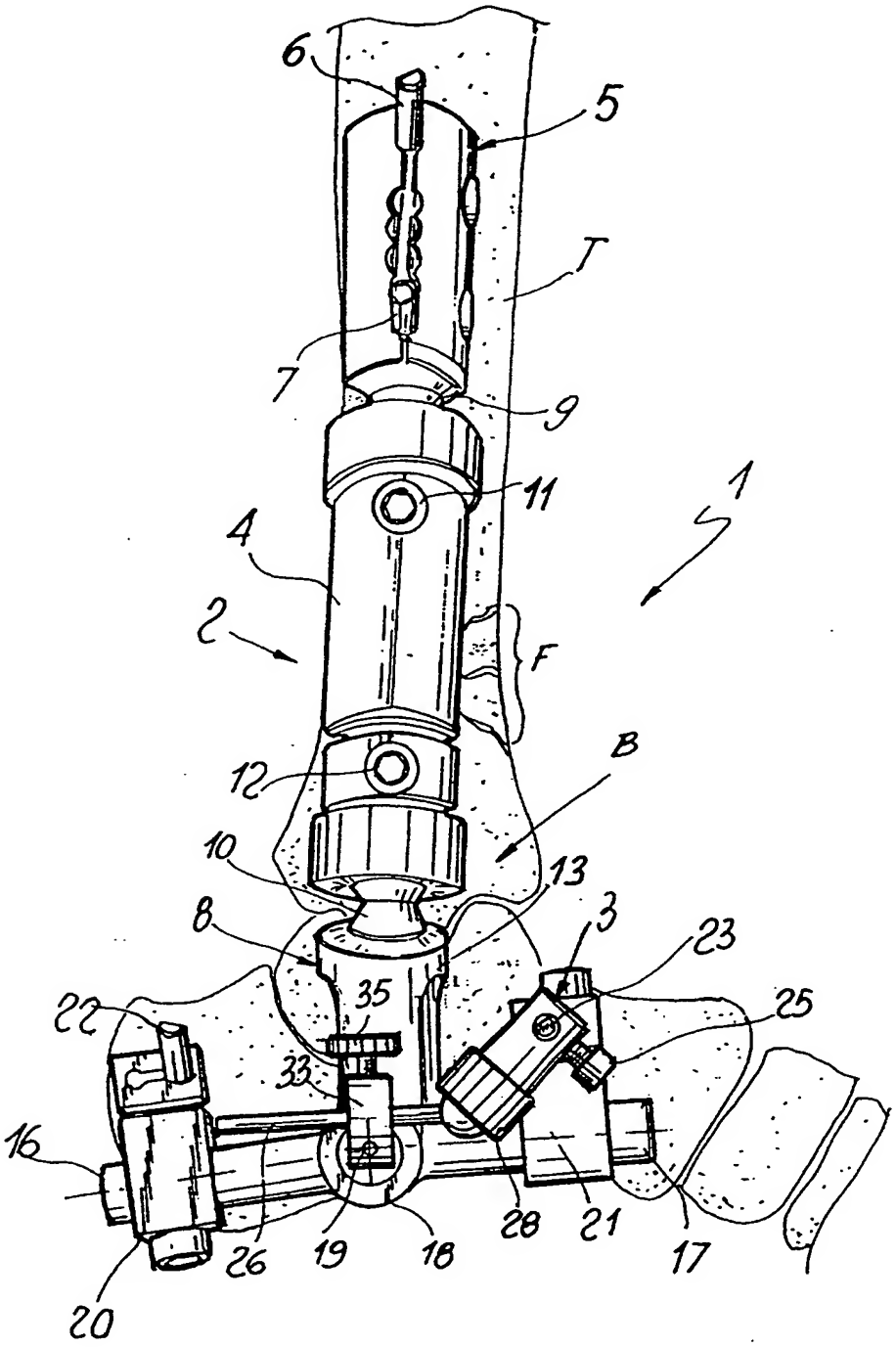


Fig. 1

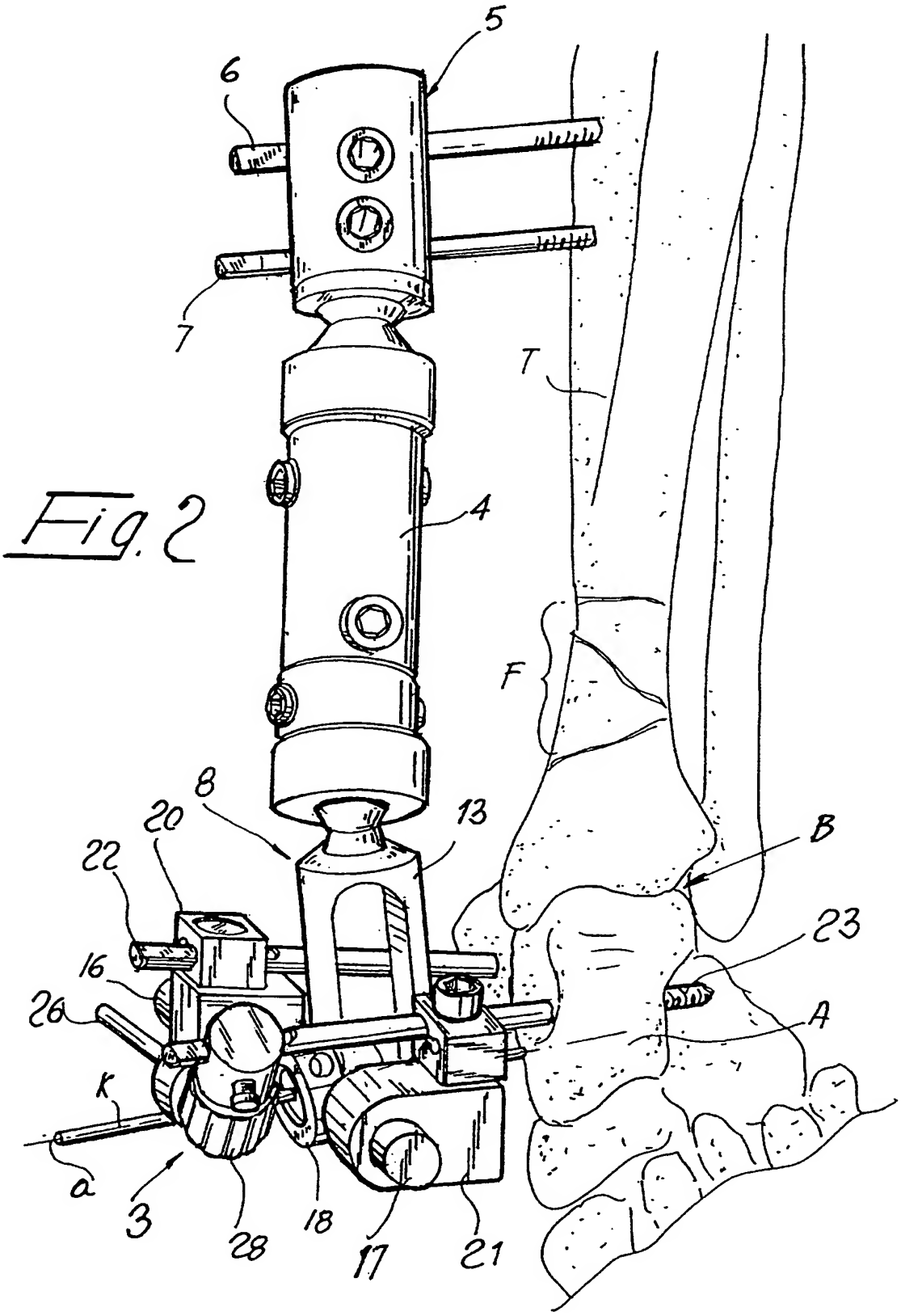


Fig. 2

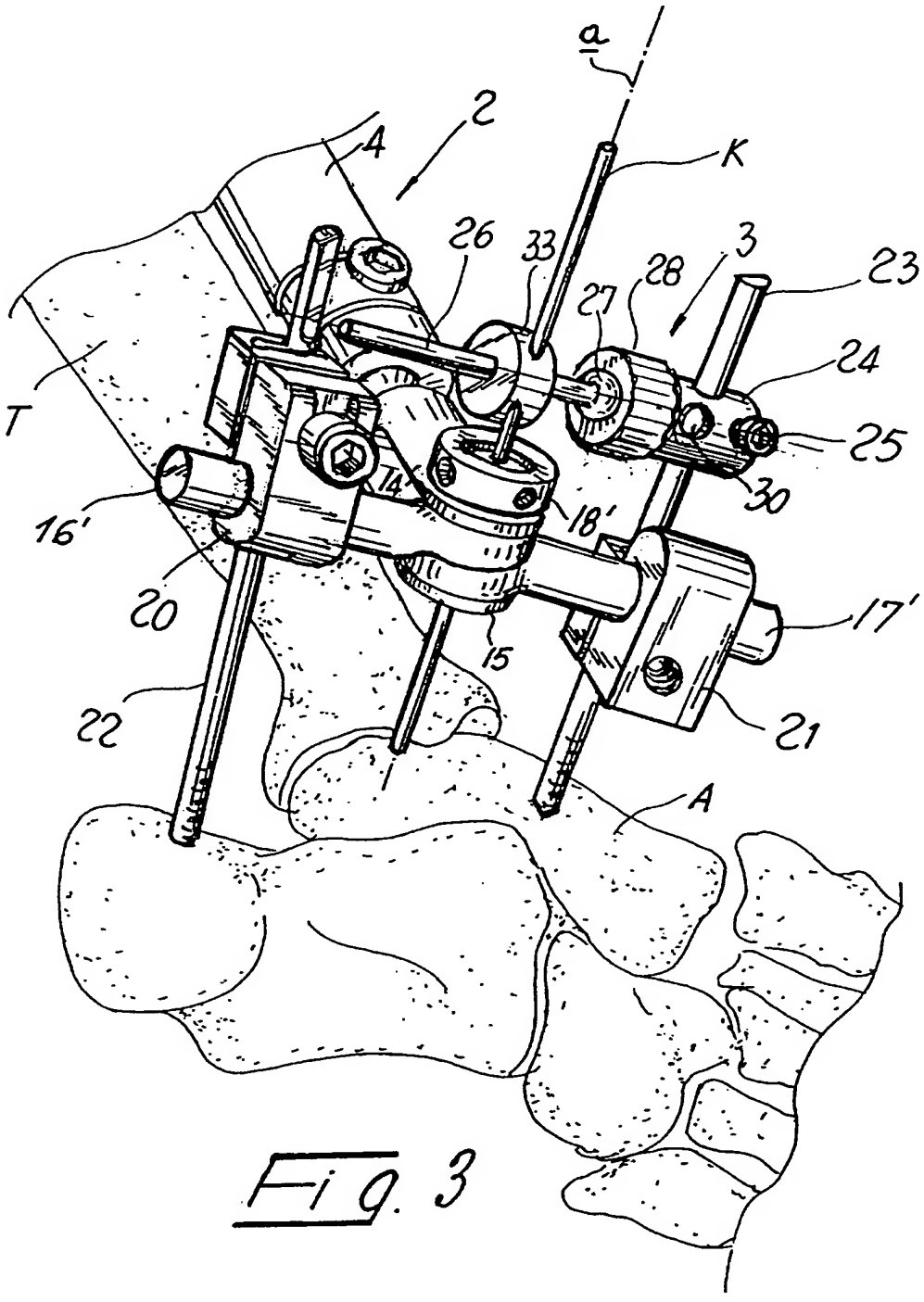


Fig. 3

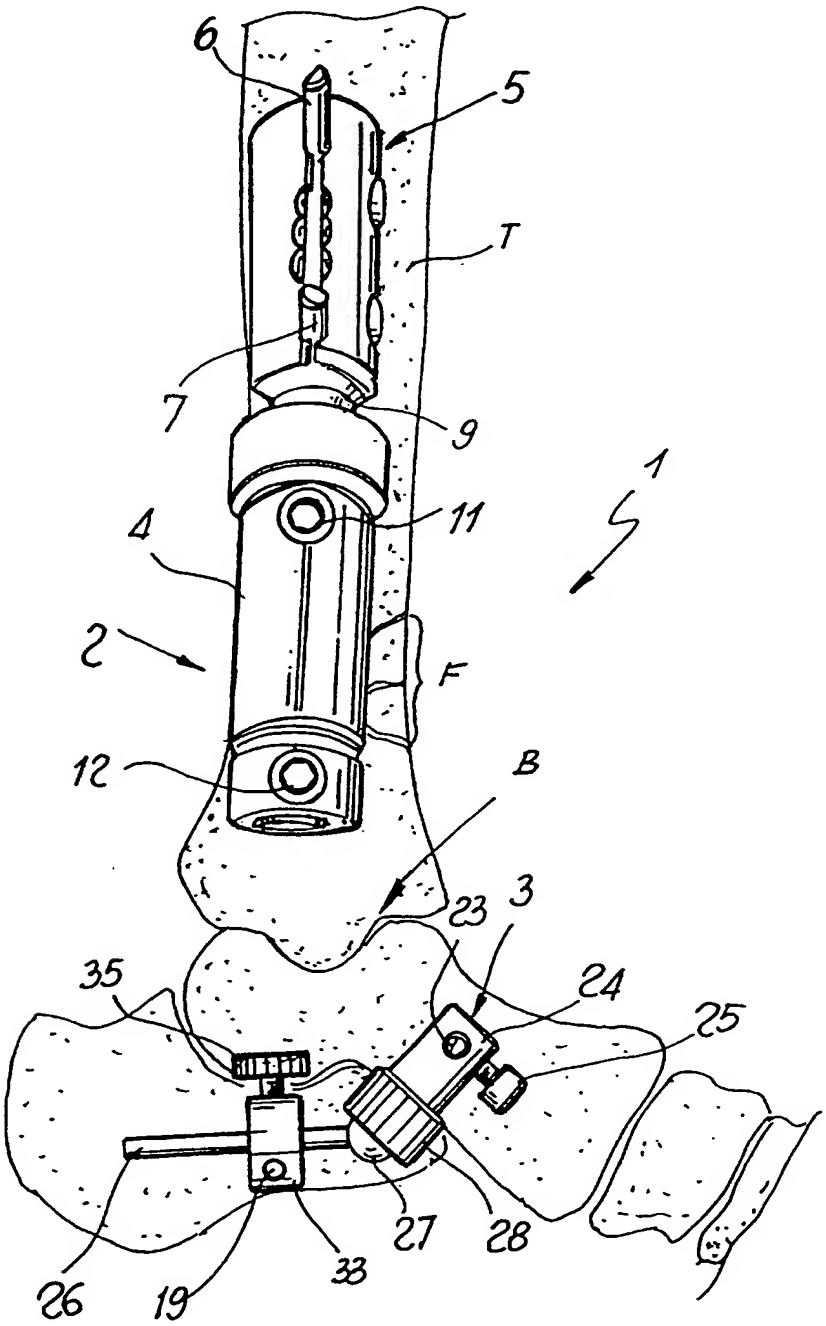


Fig. 4

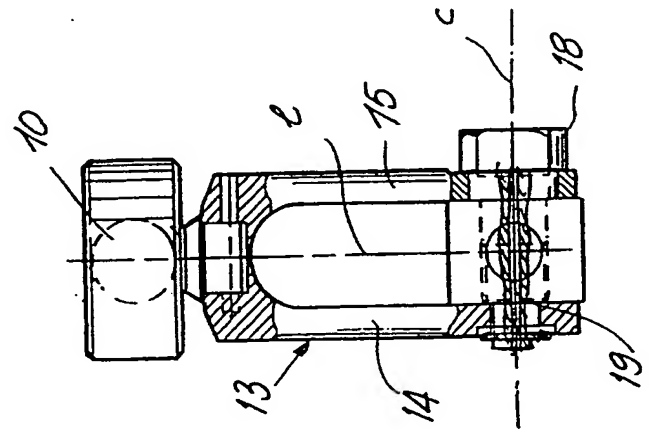


Fig. 6

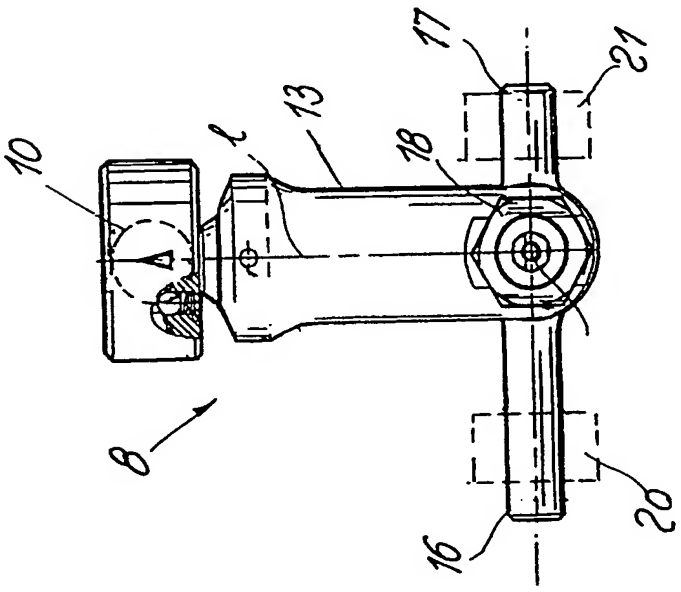


Fig. 5

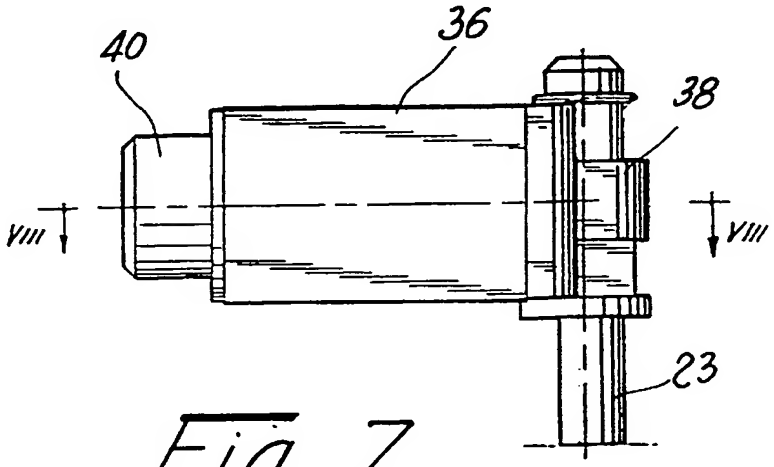


Fig. 7

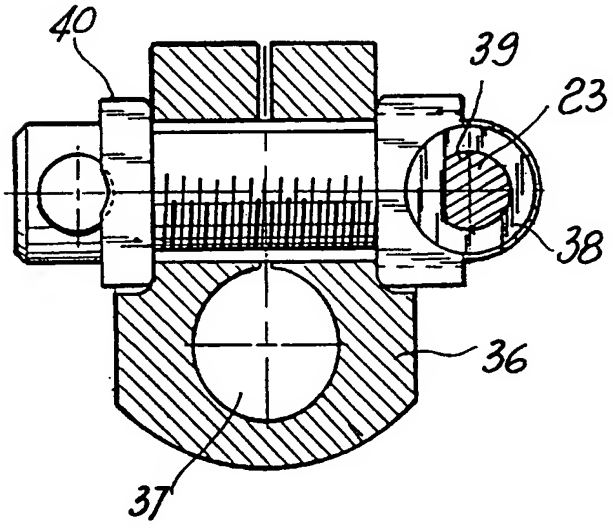


Fig. 8

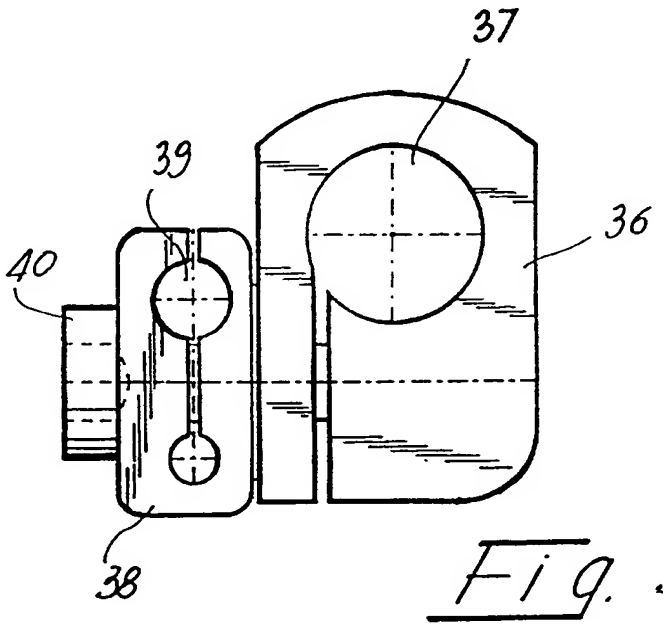


Fig. 9

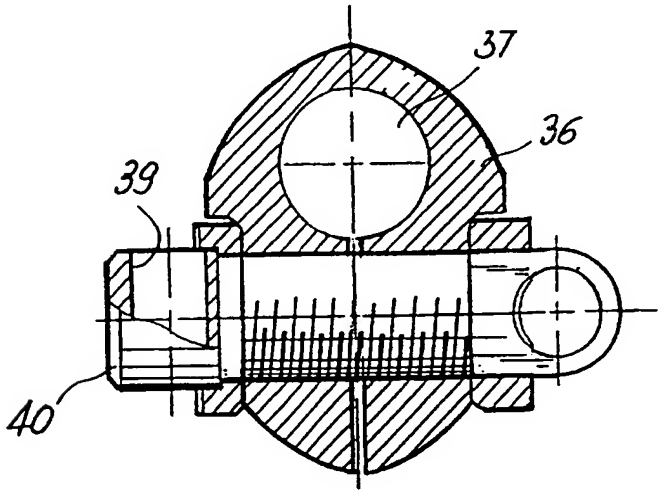


Fig. 10

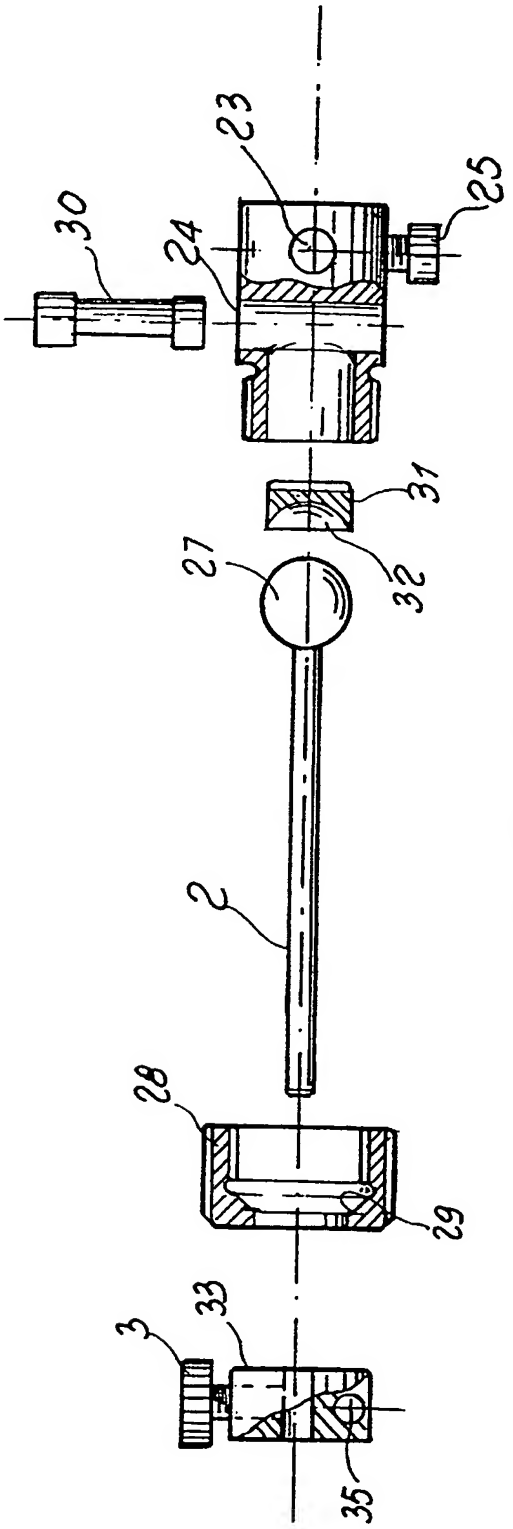
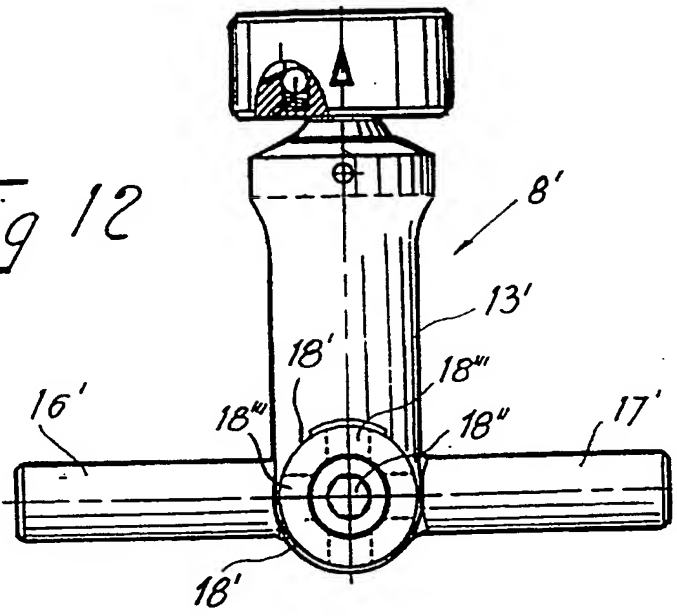


Fig. 11

Fig 12



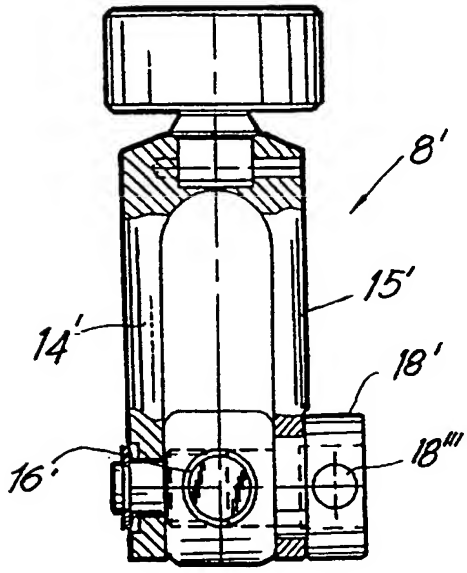


Fig. 13

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(57) Abstract

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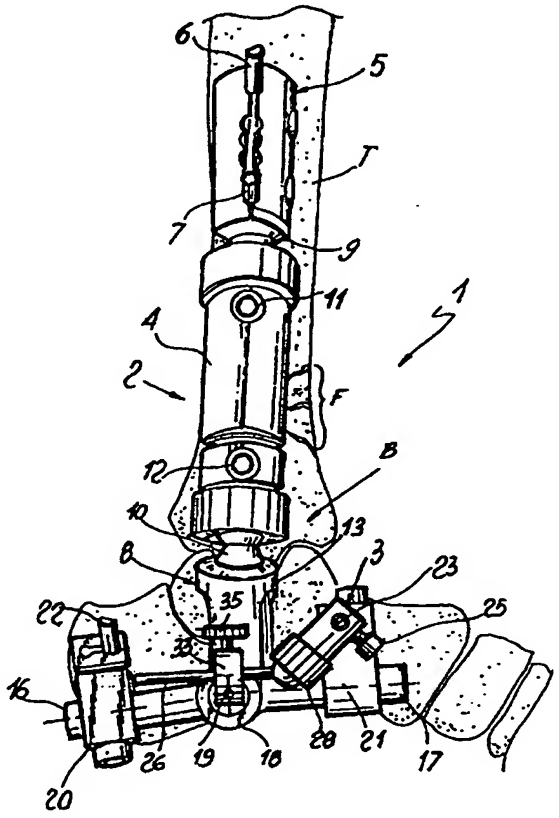

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INTERNATIONAL SEARCH REPORT

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A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61B17/64

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0 628 289 A (HARDY JEAN MARIE) 14 December 1994 see column 1, line 46 - line 52 see column 8, line 43 - line 48 see figures 49-51 ---	1-11
A	US 4 696 293 A (CIULLO JEROME V) 29 September 1987 see column 1, line 23 - line 31 see column 2, line 64 - column 3, line 7 see column 4, line 22 - line 25 see figure 11 --- -/--	1-11

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

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Date of the actual completion of the international search	Date of mailing of the international search report
6 March 1997	14.03.97
Name and mailing address of the ISA European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+ 31-70) 340-2040, Tx. 31 651 epo nl, Fax (+ 31-70) 340-3016	Authorized officer Chabus, H

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Inter. nal Application No
PCT/EP 96/04113

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0 414 633 A (JAQUET ORTHOPEDIE) 27 February 1991 see column 3, line 23 - line 29 see column 4, line 13 - line 16 see column 7, line 58 - column 8, line 6 see figures 1,2 -----	1

1

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/EP 96/04113

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 12
because they relate to subject matter not required to be searched by this Authority, namely:
PCT Rule 39.1 (iv)Method for treatm. of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searches without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inter. nal Application No
PCT/EP 96/04113

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 0628289 A	14-12-94	FR 2705882 A	09-12-94
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		JP 3092151 A	17-04-91
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